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510(k) Summary of Safety and Effectiveness

Line Extension to the Secur-Fit™ Max and Secur-Fit™ Plus Max Hip Stem

Proprietary Name:	Secur-Fit™ Max and Secur-Fit™ Plus Max Hip Stems
Common Name:	Artificial Hip Components
Proposed Regulatory Class:	Class II
Classification:	Hip joint, metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prostheses, 21 CFR §888.3353.
Device Product Code:	87 MEH, Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calicum-Phosphate and 87 LZO: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented
For Information contact:	Karen Ariemma, Senior Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Telephone: (201) 831-5718 Fax: (201) 831-6038 Email: karen.ariemma@stryker.com
Date Summary Prepared:	June 27, 2005

Device Description

The subject Secur-Fit™ Max Hip and Secur-Fit™ Plus Max Hip Stems are titanium alloy hip stems. The hip stems have a Commercially Pure Titanium arc deposited circumferential coating with a PureFix™ HA hydroxylapatite surface treatment. The stems are intended for cementless fixation and are available in stem sizes 4-14 and neck lengths ranging from 25mm to 40mm. The stems are available with either a 127° or 132° neck angle. The Secur-Fit™ Max Hip stems have a tapered distal geometry. The Secur-Fit™ Plus Max Hip Stems have a fluted and slotted distal geometry.

Device Modification

This Secur-Fit™ Max and the Secur-Fit™ Plus Max Hip Stems were cleared for use with metal and Alumina Ceramic Heads. This submission adds the use of a C-Taper Biolox® Delta Ceramic Femoral Head with the Secur-Fit™ Max and the Secur-Fit™ Plus Max Hip Stems.

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Intended Use

The Secur-Fit™ Max and the Secur-Fit™ Plus Max Hip Stems are single-use devices and are intended for cementless fixation within the prepared femoral canals of patients requiring hip arthroplasty.

Indications for Use

The indications for use of the Osteonics® Secur-Fit™ HA and Secur-Fit™ Plus Hip Stems as a Total Hip Replacement include:

- Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Substantial Equivalence

The features of the subject components are substantially equivalent to the predicate devices based on similarities in intended use and design. Mechanical testing demonstrates substantial equivalence of the subject components to the predicate devices in regards to mechanical strength. In addition, the intended use, manufacturing methods, packaging, and sterilization of the predicate and subject components are identical. The material of the subject Secur-Fit™ Max and the Secur-Fit™ Plus Max Hip Stems remains unchanged. The subject ceramic femoral heads are fabricated from Zirconia toughened Alumina.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2005

Ms. Karen Ariemma
Senior Regulatory Affairs Specialist
Howmedica Osteonics Corp.
Mahwah, New Jersey 07430

Re: K051738
Trade/Device Name: SECUR-Fit™ Max and SECUR-FIT™ PLUS Max Hip Stems
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: II
Product Code: LZO, MEH
Dated: June 27, 2005
Received: June 28, 2005

Dear Ms. Karen Ariemma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost, Ph.D
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: SECUR-FIT™ Max and SECUR-FIT™ PLUS Max Hip Stems

Indications For Use:

The Secur-Fit™ Max and Secur-Fit™ Plus Max Hip Stems are single-use devices and are intended for cementless fixation within the prepared femoral canals of patients requiring hip arthroplasty.

The indications for use of the Secur-Fit™ Max and Secur-Fit™ Plus Max Hip Stems as a Total Hip Replacement include:

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- Treatment of non-union, femoral neck and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K051738